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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,631	12/31/2003	Heinz-Werner Kleemann	DEAV2002/0094 US CNT	8300
5487	7590	07/19/2007		
ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			EXAMINER ANDERSON, REBECCA L	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 07/19/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/749,631

Applicant(s)

KLEEMANN ET AL.

Examiner

Rebecca L. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 7-19, 21-32 and 34-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 6, 20 and 33 is/are rejected.
- 7) ☒ Claim(s) 1-6, 20 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37-CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to: See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claims 1-48 are currently pending in the instant application. Claims 1, 2, 5, 6, 20 and 33 are rejected, claims 1-6, 20 and 33 are objected and claims 7-19, 21-32 and 34-48 are withdrawn from consideration as being for non-elected subject matter. The finality of the previous office action has been withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5 March 2007 has been entered.

Petition Decision

Applicants' petition to review the restriction requirement filed December 13, 2006 was granted in the Petition Decision of 6/26/07. Therefore, according to the petition decision the examiner is in error in respect to setting forth a scope of elected subject matter of Group I to which the examination would be limited based on the species identified and therefore, the examiner will follow the guidelines of MPEP 803.02 wherein once a species is elected it is examined for compliance with all applicable statutes for patentability and if compliance is found, then the examination is expanded to a reasonable number of related species to determine whether they also comply with the statute.

The petition states that the examiner will also consider applicants' amendment filed 5 March 2007. Therefore, the amendment to the claims has been entered and the examiner will follow the guidelines of MPEP 803.02. The finality of the previous office action has been withdrawn, and the examiner has followed MPEP 803.02.

Election/Restrictions

As per the petition decision, the examiner will determine whether the entire scope of the claims is patentable according to MPEP 803.02. Applicants' elected species of 3-guanidinecarbonyl-1-(7-methyl-7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-indole appears allowable over the prior art of record. Therefore, according to MPEP 803.02: should no prior art be found that anticipated or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipated or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The search of the Markush-type claim has been extended to include the products of the formula I wherein:

R1, R2, R3,n, Ra, Rb and R4 are as found in claim 1 and **Ar** is 7H-pyrrolo-[2,3-d]-pyrimidine, which may be linked via any of its positions and which is substituted in at least one of its positions by alkyl having 1, 2, 3, 4, 5 or 6 carbon atoms, halogen, nitro, NRaRb, alkylcarbonylamino having 1,2,3 or 4 carbon atoms, hydroxyl, alkoxy having 1,2,3,4,5 or 6 carbon atoms, S(O)nR4, Co2H, alkoxycarbonyl having 1, 2, 3, 4, 5 or 6 carbon atoms, alkylcarbonyl having 1,2,3,4,5 or 6 carbon atoms, CONRaRb, CN, polyfluoroalkyl having 1,2,3 or 4 carbon atoms, polyfluoroalkoxy having 1,2 or 3 carbon

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atoms or SO₃H, or a racemic mixture, enantiomer, diastereomer, or tautomer of such compound, or a mixture thereof, or a pharmaceutically acceptable salt of such compound, racemic mixture, enantiomer, diastereomer, tautomer, or mixture.

Additionally, the search of the Markush-type claims have been extended to the non-elected species of formula (I) wherein Ar is quinoline.

As prior art has been found which anticipates the above identified nonelected species wherein Ar is quinoline, the Markush-type claims are rejected as follows and the subject matter of the claims drawn to nonelected species held withdrawn from consideration. Claims 1-6, 20 and 33 have been examined to the extent that they are readable on the elected embodiment and the above identified nonelected species. Since art was found on the nonelected species, subject matter not embraced by the elected embodiment or the above identified nonelected species is therefore withdrawn from further consideration.

It has been determined that the entire scope claimed is not patentable.

Additionally, as per the petition decision of 6/26/07, the restriction between Groups I-III is considered proper and is FINAL. In accordance with MPEP 821.04, rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims.

Response to Arguments

Applicant's arguments filed 6/26/2006 have been fully considered but they are not persuasive. In regards to the 35 USC 103(a) rejection applicant argues that the examiner fails to provide any motivation to modify the prior art compounds. Applicants' argue that Lang does not generically overlap with the claimed invention as Lang does not disclose either the guanidyl substitution at position 3 or the N-bicycloheteraryl substituent. This is not persuasive as Lang does disclose the guanidyl substitution at position 3, see preferences wherein one of the substituents R(1) to R(6) is CO-N=C(NH₂)₂(column 2). Additionally, preferences towards N-bicycloheteraryl is found in Lang wherein on columns 3 and 4 wherein R(8) can be quinolyl or isoquinolyl. Applicant argues that there must be some teaching or suggestion or motivation in the prior art to make the specific combination that was made by applicant and Applicant argues that there is no rationale for why one would have been motivated to modify the prior art to put the guanidyl substituent at position 3 or the N-bicycloheteraryl substituent. This argument is not persuasive as the prior art of Lang provides preferences towards the guanidyl at position 3 and provides preferences to quinolyl for a substituent on the nitrogen of the indole. It is these preferences along with the utility of the compound which provides the motivation to modify the prior art. Applicant argues that Lang does not disclose N-bicycloheteraryl substituents. This argument is not persuasive as Lang does disclose N-bicycloheteraryl substituents in preferred embodiments, see columns 3 and 4. Applicant argues that the mere possibility does not provide motivation and the examiner used improper hindsight. This argument is not

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persuasive as mere possibility is not the motivation behind the 35 USC 103(a) rejection, but the preferences towards compounds as instantly claimed coupled with the utility of the compound. The motivation would be to the expectation of preparing more biologically active benzo-fused heterocyclic compounds useful as diagnostic agents and as pharmaceutical compositions for the treatment of conditions such as atherosclerosis.

Claim Objections

Claims 1-6, 20 and 33 are objected to as containing non-elected subject matter. Claims 1-6, 20 and 33 presented drawn solely to the elected invention as identified *supra* would overcome the instant objection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Claims 1, 2, 5, 6, 20 and 33 is rejected under 35 U.S.C. 103(a) as being obvious over LANG et al., US Patent No. 5,852,046.

Determining the scope and contents of the prior art

US Patent No. 5,852,046 discloses benzo-fused heterocyclic compounds having a 5-membered ring and their use as diagnostic agents and medicaments on column 1, lines 15-17. The benzo-fused heterocyclic compounds having a 5-membered ring are of the formula I wherein X can be N or CR(6); Y can be oxygen, S or NR(7); A and B together are a bond or are both hydrogen; one of the substituents R(1) to R(7) is $\text{-CO-N=C(NH}_2\text{)}_2$; the other respective substituents R(1) to R(6) are such as H or (C1-6)alkyl; n is zero to 10; R(7) can be hydrogen or R(8)-CnH2n; and R(8) can be hydrogen, (C2-6)alkenyl, phenyl, 1- or 2-naphthyl, pyridyl, quinolyl or isoquinolyl (columns 1 and 2). Preferences towards the subject matter of applicants' instant invention are found in the preferences wherein Y is NR(7) (column 2, line 29); one of the substituents R(1) to R(6) is $\text{CO-N=C(NH}_2\text{)}_2$; A and B are a bond (column 2, line 30); n is zero to 4 (column 2, line 41); R8 can be quinolyl or isoquinolyl (column 2, line 63). Further preferences to compounds which are positional isomers of the subject matter of the claimed invention are found in preferred embodiments on column 3 wherein X is CR(6); Y is NR(7); A and B together can form a bond; R(1) is $\text{-CO-N=C(NH}_2\text{)}_2$; n can be zero; R(8) can be quinolyl or isoquinolyl; and R97) can be R(8)-CnH2n. Further preferences are found on columns 3 and 4 wherein R(8) can be quinolyl or isoquinolyl and can be substituted by 1 to 3 substituents chosen from the group consisting of F, Cl, Br, I, CF3, etc.

Ascertaining the differences between the prior art and the claims at issue

The difference between the prior art and the subject matter of the claims at issue is that the prior art does not specifically disclose a specific compound of the instantly

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claimed formula (I). However, the prior art discloses the compounds of the formula (I), which generically overlap with applicants' instantly claimed products and generically overlaps with positional isomers of applicant's instantly claimed products. Furthermore, the prior art does disclose preferences towards applicants' instantly claimed products and preferences towards positional isomers of applicants' instantly claimed products which provides direction and motivation to prepare the subject matter of applicants' instantly claimed invention.

Resolving the level of ordinary skill in the pertinent art

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the compounds within applicants instant compound of formula I when faced with the prior art of Lang et al. since the prior art discloses products, diagnostic agents and pharmaceutical compositions which generically overlap with the subject matter of the claimed invention and positional isomers thereof and provides direction towards applicants' subject matter of the instant claims within the preferred embodiments. The motivation would be to the expectation of preparing more biologically active benzo-fused heterocyclic compounds useful as diagnostic agents and as pharmaceutical compositions for the treatment of conditions such as atherosclerosis. Furthermore, nothing unobvious is seen in substituting the claimed isomer for the structurally similar isomer, as taught by LANG et al. since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

Conclusion

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday from 6:00am until 2:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9 July 2007